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OFFICE OF THE VICE PRESIDENT – RESEARCH AND GRADUATE STUDIES

OFFICE OF THE PRESIDENT
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May 21, 2018

Administrator Scott Pruitt
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Docket No. EPA-HQ-OA-2018-0259: Strengthening Transparency in Regulatory Science (April 30, 2018)

Dear Administrator Pruitt:

I write on behalf of the University of California (UC) system with regard to the proposed rule, "Strengthening Transparency in Regulatory Science," published in the *Federal Register* by the Environmental Protection Agency (EPA) on April 30, 2018.

The UC system comprises ten research-intensive campuses, six medical schools, and three affiliated U.S. Department of Energy national laboratories. As a system, UC receives approximately $5 billion annually of extramural awards to support research conducted throughout all UC locations. The UC system is committed to conducting research according to its system-wide policy, which states that "[a]ll persons engaged in research at the University are responsible for adhering to the highest standards of intellectual honesty and integrity in research."[1]

The aim of the EPA's proposed rule is to make "data and models underlying the science publicly available in a manner sufficient for validation and analysis." UC strongly supports the open exchange of information to ensure the validity of and to build upon research. However, we believe the proposed rule is unnecessary, makes erroneous assumptions about the scientific process, and would inadvisedly limit the kind of scientific research that should be considered in decisions affecting human health and our environment.

The EPA's proposal to demand that underlying data and models be publicly accessible as a condition of its regulatory decision-making can already be satisfied under the current version of the Freedom of Information Act (FOIA). In 1999, a rider, often called the Shelby Amendment or Data Access Act, mandated that Circular A-110[2] be amended to ensure that all published data from federally sponsored research used for policy and rulemaking be made available through procedures established under the FOIA. This process accomplishes EPA's goal of allowing the public to verify the soundness of science underlying policy decisions. A Congressional bill similar in intent to the EPA's proposed rule – the HONEST Act – was offered and defeated last year because of serious concerns raised by members of Congress about the negative impact the bill would have by significantly reducing the amount of scientific

[1] University of California Office of the President. University Policy on Integrity in Research 6-19-1990. Available: https://www.ucop.edu/academic-personnel-programs/_files/apm/apm-190-b.pdf

[2] The referenced language is now located at 2 CFR 200.337, the corresponding section of Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (the successor regulations that incorporate the contents of OMB Circular A-110).

evidence that EPA can consider when adopting regulatory standards to protect public health and the environment.

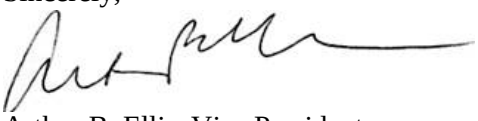
The proposed EPA rule requires public availability of data and models from scientific studies as the basis of decision-making, but does not recognize adequately the importance of the context for the studies nor privacy concerns. In particular, the design, methods, and assumptions of research studies are vitally important for validating scientific results and are typically addressed through peer review prior to publication. Once the results of the research study are published, the scientific community and the public at large may respond to the study and challenge the premises, methodology, analyses, and/or conclusions. Such challenges could include other research aimed at testing the validity of the findings. This process is one of the long-standing fundamental checks on the validity of scientific research.

The EPA's rule would furthermore restrict the research that could be considered in decisions affecting the health and well-being of people and the environment because of privacy considerations. In many cases, releasing data would be a violation of health privacy laws and confidentiality agreements with human subject participants. For example, many public health studies rely on participants sharing sensitive health data and medical records. Researchers could redact and anonymize personal health data, involving considerable time, cost, and administrative burden, but there are limits as to how much an individual's identity can be protected, especially in small communities where basic identifiers may be enough to recognize an individual. Discarding studies from the regulatory decision-making process to protect sensitive information would exclude relevant and important science, compromising public health.

We are also concerned that an incomplete pool of scientific evidence could skew regulatory decision-making toward studies that are less rigorous and trustworthy even if data were available. This concern is exacerbated by the proposed language at subparts §30.2 and §30.9, which allow the EPA to selectively choose studies to meet its agenda. Subpart §30.2 contains an *a priori* criterion of "pivotal regulatory science" while §30.9 gives the EPA Administrator discretion to issue exemptions from the policy on a case-by-case basis. These sections are vague on how and by what measures determinations would be made, opening the door for drawing upon studies driven by unknown interests or by political considerations rather than, as EPA's Mission Statement notes, "…the best available scientific information."[3]

There are many ways to increase transparency in regulatory decision-making, but limiting scientific research should not be one of them. We are certain that it is not the EPA's intent to appear arbitrary in its regulatory decision-making, but we believe that this will, unfortunately, be the result if the proposed rule goes into effect. The University of California urges the EPA to reconsider and rescind the proposed rule, as in our view it promotes opacity rather than transparency.

Sincerely,



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[3] United States Environmental Protection Agency. Our Mission and What We Do. Available: https://www.epa.gov/aboutepa/our-mission-and-what-we-do